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| 10/789,492 | 02/26/2004 | Ramez Emile Nicola Shehada | 64693-094 | 7995 |
| 33401 7590 08/19/2008 MCDERMOTT WILL & EMERY LLP 2049 CENTURY PARK EAST 38th Floor LOS ANGELES, CA 90067-3208 | | | EXAMINER TOYTH, KAREN E | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/789,492

Applicant(s)

NECOLA SHEHADA ET AL.

Examiner

KAREN E. TOTH

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 11 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 15-22, 24-27, 62, 68, 70, 75 and 78-87 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 62, 68, 70, 75 and 81-87 is/are allowed.
- 6) ☒ Claim(s) 1, 15-22, 24-27, 78-80 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

2. Claims 1, 15-19, 21, 22, 27, and 78-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prutchi (US Patent 5730125) in view of Chance (US Patent 5954053).

Regarding claim 1, Prutchi discloses a system for sensing the oxygenation of two separate areas of tissue (figure 9) using a first sensing system on one side of the implanted device (elements 72A, 74A, 76A) and a second system on the opposite side of the implanted device (elements 72B, 74B, 76B), and comparing the oxygenation measurements obtained from the two sensing systems (column 11, lines 11-27). Prutchi does not disclose the oxygenation comparison being used to determine if the condition of one of the tissue areas is "normal".

Chance teaches a system for sensing the oxygenation of two tissue areas using separate sensing systems that compares the oxygenation measurements to determine the condition of one area with respect to the other (column 26, lines 4-60), in order to determine the state of the measured tissues. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the system of Prutchi to determine the condition of one tissue area with respect to the other, as taught by Chance, in order to determine the state of the monitored tissue.

The Examiner notes that the invention is claimed as being implanted between transplanted and native tissues in a patient; any sensor having the physical structure as disclosed above may be implanted in a patient such that it is located between transplanted and native tissues. Further, a native tissue is inherently "different" from a transplanted tissue, so it is not clear what applicant intends by adding this descriptor. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Regarding claim 15, Prutchi further discloses elements for transmitting energy to the tissue proximate the sensing surfaces (elements 72a, 72b, 74a, 74b).

Regarding claim 16, Prutchi further discloses the system comprising additional, non-oxygenation, sensors (column 8, lines 12-27).

Regarding claim 17, Prutchi further discloses embedding the sensing systems behind optically transparent material (column 9, lines 56-65).

Regarding claim 18, Prutchi further discloses a processing system in the housing (element 62).

Regarding claims 19, 21, and 22, Prutchi further discloses an external processing system and an antenna for sending or receiving signals (column 13 line 45 - column 14 line 23).

Regarding claim 27, Prutchi further discloses a protrusion from the device (element 25) that can hold it in place. Though not disclosed as an anchor, the protrusion would inherently help stabilize the device's position.

Regarding claims 78-80, the processing system is configured to determine the tissue condition regardless of the signal origin.

3. Claims 1, 15-19, 21, 22, 24, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chance in view of Prutchi.

Regarding claim 1, Chance discloses a system for sensing the oxygenation of a particular tissue area in relation to another tissue area comprising first and second sensing systems configured to sense the oxygenation of first and second tissues, and a processing system that compares the oxygenation values to determine the condition of one tissue with respect to the other (column 26, lines 4-60). Chance does not disclose the system comprising a housing with one sensing system for sensing the oxygenation of the first tissue on one side and a second sensing system for sensing the oxygenation of the second tissue on the opposite side.

Prutchi teaches a system for sensing tissue oxygenation comprising a housing (figure 9) having a first oxygenation sensing system on one side of the device (elements 72A, 74A, 76A) and a second oxygenation sensing system on the opposite side (elements 72B, 74B, 76B), in order to perform oxygenation sensing of separate areas of tissue while minimizing the number of implanted devices. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the

device of Chance with the sensing systems on opposite sides of a single enclosure, as taught by Prutchi, in order to minimize the number of implanted components.

The Examiner notes that the invention is claimed as being implanted between transplanted and native tissues in a patient; any sensor having the physical structure as disclosed above may be implanted in a patient such that it is located between transplanted and native tissues. Further, a native tissue is inherently "different" from a transplanted tissue, so it is not clear what applicant intends by adding this descriptor. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Regarding claim 15, Chance further discloses a transmitting element that delivers energy to the tissues adjacent the sensing surfaces (column 26, lines 31-33).

Regarding claim 16, Prutchi further discloses an additional sensing system for sensing a tissue property other than oxygenation (column 8, lines 33-42), in order to allow more complete monitoring of the tissue. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Chance with an additional non-oxygenation sensor, as taught by Prutchi, in order to allow more complete monitoring of the tissue.

Regarding claim 17, Prutchi further discloses the sensing systems being located behind optically transparent material (column 7, lines 13-34), in order to protect the

sensing systems while allowing transmission. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Chance in view of Prutchi with the sensing systems behind optically transparent material, as taught by Prutchi, in order to protect the systems and still allow signal transmission.

Regarding claim 18, Prutchi further teaches including the processing system in the implanted device (figure 2), in order to consolidate operations. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Chance in view of Prutchi with the processing system in the implanted device, as taught by Prutchi, in order to consolidate operations.

Regarding claim 19, Chance further discloses an external processing system (figure 24).

Regarding claims 21 and 22, Prutchi further discloses an antenna for sending and receiving signals (column 13 line 45 to column 14 line 17), in order to allow implanted components to communicate with external components. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Chance in view of Prutchi with an antenna, as taught by Prutchi, in order to allow communications between implanted and external components.

Regarding claims 24 and 25, Chance further discloses a display for displaying sensing system data or data representing the comparison between data (column 26, lines 4-60).

4. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Prutchi in view of Chance, as applied to claims 1, 15-19, 21, 22, 27, and 78-80 above, and further in view of Gord (US Patent 5999848).

Regarding Claim 20, Prutchi in view of Chance discloses all the elements of the current invention, as applied to Claim 1, except for the system including an antenna for receiving power.

Gord teaches an implantable device with an antenna for receiving power signals (column 5, lines 34-36) in order to provide power for operation. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Prutchi in view of Chance with the power receiving capability of Gord, in order to provide power for operation.

5. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Prutchi in view of Chance, as applied to claims 1, 15-19, 21, 22, 27, and 78-80 above, and further in view of Benaron (US Patent 5987346).

Prutchi in view of Chance discloses all the elements of the claimed invention, as disclosed above, except for using optical fibers in the sensing systems.

Benaron teaches an oxygenation sensing system that uses optical fibers (column 4, lines 37-48; column 13, lines 11-28), in order to efficiently transmit energy for parameter measurement. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used optical fibers, as taught by Benaron, in

the system of Prutchi in view of Chance, since it is merely a substitution of one sensing system for an equivalent.

Allowable Subject Matter

6. The following is a statement of reasons for the indication of allowable subject matter:

The prior art of record fails to anticipate or make obvious the methods of claims 62, 68, 70, and 81-83 including, *inter-alia*, positioning an icon on a display to show the position of a sensing device within a body when receiving information from a device having two sensing systems.

The prior art of record fails to anticipate or make obvious the structure of claim 75, including, *inter-alia*, including a display that is configured to depict an icon representing a device on the display relative to a depiction of the tissue to indicate the position of a device within a body when sensing using an implantable sensor having two sensing systems.

The prior art of record fails to anticipate or make obvious the method of claims 84-87, including, *inter-alia*, determining the condition of a transplanted tissue by using a device having first and second oxygenation sensing systems to measure oxygenation of the transplanted tissue and an adjacent native tissue, where the device is implanted between the transplanted and native tissues, comparing the oxygenation measurements, and determining whether the transplanted tissue is in a "normal" condition based on the comparison.

Arnone (US Patent Application Publication 2003/0149346) discloses comparing the absorption values of tissue to determine the location of areas that are diseased. Arnone does not disclose using the comparison to determine the current condition of an already known abnormal area.

Masychev (US Patent 6123719) discloses comparing reflectance measurements to a standard to determine the condition of tissue. Masychev does not disclose comparing measured areas to each other to determine tissue condition.

Mannheimer (US Patent 5218962) discloses comparing oxygenation measurements from multiple regions to each other, but uses the comparison to assess the accuracy of measurements.

Response to Arguments

7. Applicant's arguments filed 11 June 2008 have been fully considered but they are not persuasive.

Applicant has attempted to make claim 1 and its dependents allowable by attempting to provide a device for performing the steps of allowable method claim 84; this has not resulted in an allowable claim, since, as discussed above, there must be some structural difference between the claimed invention and the prior art. Prutchi is capable of being performing the intended use, it merely has not been disclosed as doing so. As such, the actual method is novel, but the device for performing it is not.

Applicant has argued that Prutchi does not compare levels of oxygenation; the Examiner disagrees, since the compared reflectance values are inherently

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representative of oxygenation. Applicant has also argued that Chance does not teach monitoring two different tissues; again, this is a recitation of intended use. Chance's system may be positioned anywhere, including locations where it may monitor two different tissues. Applicant also contends that Chance does not monitor oxygenation; the Examiner again disagrees, since Chance clearly states that the measurements may be representative of oxygenation.

The rejections stand as FINAL.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAREN E. TOTH whose telephone number is (571)272-6824. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert L. Nasser Jr/
Primary Examiner, Art Unit 3735

/K. E. T./
Examiner, Art Unit 3735